UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

DANIEL BOURBIA, individually and on behalf of all others similarly situated, Plaintiff, vs. S.C. JOHNSON & SON, INC., Defendant.	Civil Action No. 18-cv-03944 Hon. Paul A. Crotty

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANT'S MOTION FOR RECONSIDERATION

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PRELIMINARY STATEMENT

Plaintiff does not dispute that the Supreme Court's decisions provide three principles of conflict preemption. First, that federal "requirements" include both (1) federal statutes and regulations and (2) labeling imposed by the regulating federal agency where the laws require a premarket approval ("PMA") process in which the agency must scrutinize and judge the efficacy data adequate to support the registration application. Second, that state law "requirements" include both (1) state statutes and regulations and (2) lawsuits seeking to impose liability on the basis of the product label. Third, that the federal requirements and state law requirements conflict irreconcilably where the defendant cannot unilaterally alter the label approved via the PMA process and therefore cannot meet the standard set forth by the state law challenge, preempting such challenge.

Rather than dispute the ordinary rules of conflict preemption, or provide any argument why the operation of such rules do not bar his claims here, Plaintiff instead claims that such rules of preemption may be ignored if the regulating federal agency is the Environmental Protection Agency ("EPA") and the federal regulation is pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). Plaintiff's arguments are unfounded and betray a core misconception: that the doctrine of federal preemption leads not only to *different results* depending on the scope and extent of federal regulation, but also to *different standards* for different products and statutes, without regard to the scope and extent of federal regulation thereunder.

Plaintiff is demonstrably wrong. There is no inconsistency among the preemption results in the leading Supreme Court cases: the differing results flow from the application of the same preemption standards to differing facts and regulations. *Bates* and each of the leading Supreme Court preemption cases following it—*Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), *Wyeth v.*

Levine, 555 U.S. 555 (2009), *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), and *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013)—apply the same preemption standards. In *Bates*, the Court explicitly noted that the registration of the agricultural pesticide at issue was not the product of any efficacy review under FIFRA.[1] Accordingly, the EPA did not determine whether any relevant part of the label was true or false. The federal "requirements" were therefore limited to the statute and regulations.[2]

Next, in *Riegel*, the Supreme Court considered whether premarket review and approval of a medical device constituted a federal "requirement." The Court noted that, in a prior decision involving a medical device exempt from such review,[3] it had found that registration did not create any federal requirements. In contrast, in view of the PMA process applicable to the device at issue in *Riegel*, the Court concluded that such premarket approval "imposes [federal]

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[1] Specifically, the *Bates* Court observed:

> In a notice published years later in 1996, EPA confirmed that it had "stopped evaluating pesticide efficacy for routine label approvals almost two decades ago," and clarified that "*EPA's approval of a pesticide label does not reflect any determination on the part of EPA that the pesticide will be efficacious or will not damage crops or cause other property damage.*" The notice also referred to an earlier statement in which EPA observed that "'pesticide producers are aware that they are potentially subject to damage suits by the user community if their products prove ineffective in actual use.'" This general waiver was in place at the time of Strongarm's registration; *thus, EPA never passed on the accuracy of the statement in Strongarm's original label recommending the product's use "'in all areas where peanuts are grown.'"*

544 U.S. at 440 (emphases added) (internal citations omitted).

[2] Not surprisingly, the Court did not reach beyond the facts before it to suggest what the result would have been if FIFRA had required the EPA to review the efficacy of the agricultural pesticide at issue and to approve the label only upon determining that the manufacturer's data adequately supported the efficacy claims, as FIFRA requires with respect to public health pesticides like Defendant's Product. Likewise, the Court in *Wyeth* did not suggest what the result would have been in the absence of an FDA regulation permitting certain label changes without prior agency approval. The Court did not reach that issue until it addressed facts where the regulations did not permit unilateral label changes, in *PLIVA* and *Mutual Pharmaceutical*.

[3] In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), as in *Bates*, the Court's opinion did not state whether preemption would have applied if the medical device had undergone a PMA process. That issue was not addressed explicitly until it was presented—12 years after *Lohr*—in *Riegel.*

'requirements,'" 552 U.S. at 322, preempting efforts to impose state law "requirements" in conflict with the federal agency determinations made during the PMA process.

One year after finding preemption in *Riegel*, the Court in *Wyeth* concluded that an approved label did not preempt state law claims involving a brand-name drug, although it recognized that the Food and Drug Administration ("FDA") had approved the exact text of the label at issue: "Wyeth has failed to demonstrate that it was impossible for it to comply with both federal and state requirements. The [relevant] regulation permitted Wyeth to unilaterally strengthen its warning . . . ." 555 U.S. at 573.

In *PLIVA*, the defendant was a generic drug manufacturer who argued that state law claims were preempted because FDA regulations applicable to generic drugs did not permit any unilateral revision or strengthening of the label. In an incisive opinion, the Court found conflict preemption an inherent part of the Supremacy Clause. The Court noted that "the text of the Clause—that federal law shall be supreme, 'any Thing in the Constitution or Laws of any State to the Contrary notwithstanding'—plainly contemplates conflict pre-emption by describing federal law as effectively repealing contrary state law." *PLIVA*, 564 U.S. at 621. It concluded that plaintiff's tort claims were preempted because "state law imposed a duty . . . to take a certain action, and federal law barred them from taking that action." *Id.* at 624.

In his Opposition, Plaintiff seeks to rely on irrelevant case law involving products that were not the subject of an agency's PMA process, and agency procedures therefore did not create any federal "requirements" under the preemption analysis. (*See* Opp. at 12-13.) On the basis of such case law, Plaintiff claims "the score is 14-0." (Opp. at 13.) But Plaintiff seeks to score points under the rules of a game inapposite here. Under the Supreme Court's rules of conflict preemption, Plaintiff is held scoreless.

Plaintiff cites no case law—nor could he—in which the EPA's premarket scrutiny and approval of efficacy data supporting label claims did not impose a federal requirement for preemption purposes. Under the Supremacy Clause, the federal PMA process here imposed label requirements that preempt conflicting state law claims, such as Plaintiff's here.

ARGUMENT

I. Reconsideration is Warranted to Correct a Clear Error of Law

A motion for reconsideration may be granted for "any . . . reason that justifies relief." *Aczel v. Labonia*, 584 F.3d 52, 61 (2d Cir. 2009) (citing Fed. R.Civ.P. 60(b)(6)). A district court "has broad discretion in determining whether to grant a motion [for reconsideration]." *Simon v. City of New York*, No. 14-cv-8391, 2015 WL 4092389, at *1 (S.D.N.Y. Jul. 6, 2015) (quoting *Baker v. Dorfman*, 239 F.3d 415, 427 (2d Cir. 2000)). Such a motion is appropriate where "the moving party can point to controlling decisions or data that the court overlooked—matters, in other words, that might reasonably be expected to alter the conclusion reached by the court." *Medisim Ltd. v. BestMed LLC*, No. 10-cv-2463, 2012 WL 1450420, at *1 (S.D.N.Y. Apr. 23, 2012) (internal quotation marks omitted). A motion for reconsideration may also be granted to "correct a clear error or prevent manifest injustice." *Id.*

Plaintiff argues that reconsideration is not warranted here because Defendant's motion did not "set forth the need to correct a clear error of law or prevent manifest injustice." (Opp. at 6.) In fact, in its March 21, 2019 Opinion and Order, this Court, citing *Cipollone v. Liggett*, 505 U.S. 504 (1992), found that "[c]onflict preemption is foreclosed here . . ., since Congress enacted a provision defining the preemptive reach of FIFRA." (Opinion and Order at 9 n.3.) As discussed in Defendant's initial brief, this interpretation of *Cipollone—i.e.*, that conflict preemption is foreclosed where Congress has chosen to include an express preemption provision in the relevant federal statute—is incorrect and has been squarely rejected by the Supreme

Court.[4] In other words, claims barred by conflict preemption remain barred on that basis without regard to the existence of an express preemption provision in the relevant federal statute. Defendant has thus respectfully moved for reconsideration on the basis of this clear error of law.

Plaintiff further argues that reconsideration is not warranted here because this Court has "already considered and rejected Defendant's conflict preemption arguments." (Opp. at 2.) But that simply ignores this Court's express language finding Defendant's conflict preemption arguments "foreclosed." (Opinion and Order at 9 n.3.)

II. The Ordinary Rules of Conflict Preemption Apply Here

As noted in Defendant's initial brief, and without dispute from Plaintiff, three core principles of preemption may be synthesized from the case law: (1) federal requirements include both federal regulations and labeling imposed by the federal regulator as part of a PMA process; (2) state law requirements include lawsuits seeking to impose liability for approved labeling; and (3) these requirements irreconcilably conflict if the defendant cannot unilaterally alter the label to conform to the alleged state standard.

Conflict preemption rises or falls here on the first principle: that federal regulations and labeling imposed by a federal agency as part of a PMA process give rise to federal requirements. Most FIFRA case law involves agricultural pesticides for which the EPA has waived efficacy review. While there is little case law involving challenges to public health pesticides like the Off! Product at issue here, there is substantial case law applying conflict preemption principles to federally-regulated goods that (like the Off! Product) are subject to a rigorous agency PMA

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[4] *See, e.g.*, *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) ("According to respondents and the Court of Appeals, [*Cipollone*] held that implied pre-emption cannot exist when Congress has chosen to include an express pre-emption clause in a statute. This argument is without merit.").

process. As Supreme Court decisions applying *Bates* make clear, there is no cause to interpret federal requirements imposed under FIFRA any differently than federal requirements imposed under other statutes. As the Solicitor General explained in the United States' amicus brief on petition for a writ of certiorari in *Riegel*:

> The process of agency review under FIFRA with regard to the label language at issue in *Bates* differs in important respects from the process by which the FDA decides whether to grant premarket approval for particular Class III devices. The plaintiff farmers in *Bates* alleged that the label of a pesticide manufactured by the defendant had failed to warn of the potential for the pesticide to damage the farmers' peanut crops. Under FIFRA, EPA reviews pesticides and their labeling to determine whether the pesticide causes unreasonable adverse effects on human health or safety or the environment, *but EPA does not evaluate the efficacy of the product, including its potential to harm crops or cause other property damage, and the agency does not review the accuracy of any statements about efficacy on the proposed labeling for the product.* EPA therefore had not determined whether the label at issue in *Bates* had adequately warned farmers of the potential for damage to their crops. *In the instant case, by contrast, petitioners' challenge to the safety and efficacy of the Evergreen Balloon Catheter goes directly to matters as to which the FDA conducted a rigorous agency review in the PMA process—a review that culminated in the FDA's finding that the Evergreen Balloon Catheter does provide 'reasonable assurance of safety and effectiveness' and that the labeling is not 'false or misleading.'*

2007 WL 1511526 at *15-*16 (May 23, 2007) (emphases added) (internal citations omitted).

As the above passage makes clear, unlike the situation at issue in post-*Bates* preemption decisions such as *Riegel*, *Wyeth*, *Mutual Pharmaceutical*, and *PLIVA*, *Bates* did not address a label claim that was subject to a federal agency's PMA process, which gives rise to a federal "requirement."[5] In these post-*Bates* cases, the decisive question was whether the federal requirement was consistent with the state requirement—in *Wyeth*, there was potential consistency because the brand manufacturer had a unilateral right to amend the label (the federal

[5] In *Bates*, an amendment to FIFRA permitted the EPA to waive agency review and determination of any efficacy claim of the agricultural pesticide at issue, and therefore the EPA did not determine whether the efficacy claims were adequately supported or instead caused the product to be misbranded. The instant case presents a different situation. Here, EPA reviewed and approved SC Johnson's efficacy data and the label efficacy claims, and has determined that the Off! Product is not misbranded or otherwise in violation of FIFRA.

requirement) in a manner that would conform to the state law claim; in *PLIVA*, *Mutual Pharmaceutical*, and *Riegel*, there was no such right of unilateral amendment to the federal requirement, and therefore the conflict entailed preemption.

The Supreme Court in *Bates* had no cause to consider whether the only language on the label that was directly at issue—the express warranty—itself imposed a federal requirement, because such express warranty language was not part of any federal agency PMA process. Furthermore, *Bates* did not address the need for EPA approval for altering any label language because the defense in that case was simply that petitioners' state law claims could lead to a jury verdict that could induce the manufacturer to change its label, and the Court held that such inducements were not determinative of whether a state law rule constituted a new labeling "requirement."[6]

III. Plaintiff's Claims are Barred by Conflict Preemption

As the Supreme Court held in *Mutual Pharmaceutical*—and this Court noted in its Opinion and Order—the conflict preemption doctrine defeats state law claims where it is "impossible for a private party to comply with both state and federal requirements." 570 U.S. at 473. That means plaintiffs cannot maintain state law actions challenging a label approved via a

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[6] Where the state law claim seeks to impose liability based on the label claim itself, the state law claim is not a mere state law "inducement" to alter a label but a state law "requirement" for labeling, as the Court made clear in *Mutual Pharmaceutical*. The Court rejected the dissent's argument that New Hampshire law "'merely create[s] an incentive' to alter sulindac's label or composition . . ., but does not impose any actual 'legal obligation.'" 570 U.S. at 490-91 (citations omitted). Duties imposed by tort law are no less requirements than duties imposed by statute. The Court rejected the notion that *Bates* was "to the contrary":

> The dissent is correct that *Bates* held a Texas state-law design-defect claim not to be pre-empted. But, it did so because the design-defect claim in question was not a "requirement '*for labeling or packaging*'" and thus fell outside the class of claims covered by the express pre-emption provision at issue in that case.

Mut. Pharm. Co., 570 U.S. at 491 (emphasis in original).

federal PMA process that cannot be unilaterally amended, such as the label in *Mutual Pharmaceutical* and the label here.[7] As the Court in *PLIVA* explained:

> Before the Manufacturers could satisfy state law, the FDA—a federal agency—had to undertake special effort permitting them to do so. *To decide these cases, it is enough to hold that when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.* Here, state law imposed a duty on the Manufacturers to take a certain action, and federal law barred them from taking that action. The only action the Manufacturers could independently take—asking for the FDA's help—is not a matter of state-law concern. [Plaintiffs'] tort claims are pre-empted.

Id. at 623-24 (emphasis added). Here, no less than in *PLIVA*, SC Johnson cannot "independently satisfy" the alleged "state duties for pre-emption purposes," because it cannot amend the label claims at issue "without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency." And, as the above passage from *PLIVA* makes clear, the Supreme Court's analysis is not limited to the FDA, but applies to the FDA only because it is a federal agency—that is, the preemption analysis flows not from the federal agency being the FDA, but from the FDA being a federal agency.

In an egregious effort to portray *PLIVA* and preemption case law applying *PLIVA* as applicable only to cases addressing the Federal Food, Drug, and Cosmetic Act ("FDCA"), Plaintiff quotes two sentences of Justice Thomas's opinion entirely out of context. Plaintiff writes that the recent Second Circuit decision in *Gibbons v. Bristol-Myers Squibb Co.,* 2019 WL 1339013 (2d. Cir. Mar. 26, 2019), concerns "FDCA preemption of state law failure-to-warn

[7] Although Plaintiff argues that Defendant's reply brief failed to address conflict preemption (Opp. at 2), he ignores the fact that SC Johnson had already addressed Plaintiff's main cited authority in opposition to conflict preemption, *Ansagay v. Dow Agrosciences LLC*, 153 F. Supp. 3d 1270 (D. Haw. 2015), in its initial brief. SC Johnson was able to anticipate Plaintiff's reliance on *Ansagay* because Plaintiff had previously relied on that authority in his premotion letter to the Court.

claims in connection with generic drugs" (Opp. at 5)—in fact, it addressed a brand-name drug; it was *PLIVA* that addressed a generic drug—and that the FDCA context was important:

> This is significant because, as the Supreme Court noted, "different federal statutes and regulations may, as here, lead to different pre-emption results. We will not distort the Supremacy Clause in order to create similar pre-emotion [sic] across a dissimilar statutory scheme." *PLIVA, Inc.*, 564 U.S. at 626.

(Opp. at 5.) Justice Thomas was not suggesting that the preemption doctrine always leads to different results under different statutes, much less suggesting that his analysis did not apply equally to cases implicating federal requirements in FIFRA. Rather, his point was that *different regulations even within the same statute* (the FDCA in *Wyeth* and in *PLIVA*) may lead to different results under the same preemption standard. He recognized that the result in *PLIVA* would seem unfair to the plaintiffs, whose claim would have survived under the preemption standards if they had taken the brand name version of the *same* drug—"We acknowledge the unfortunate hand that federal drug regulation has dealt [plaintiffs], and others similarly situated," *id.* at 625 —but that the Court could not alter the Supremacy Clause in order to provide the same results to users of brand-name drugs as to users of generic drugs:

> It is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers. Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand. . . . But different federal statutes and regulations may, as here, lead to different pre-emption results. We will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme.

Id. at 626.

Justice Thomas's analysis offers no support to Plaintiff—indeed, it refutes Plaintiff's effort to rely on case law addressing agricultural pesticides that are subject to a very different regulatory regime under FIFRA from that applicable to public health pesticides like the Off! Product here. The Off! Product label was approved by the EPA under a rigorous PMA process

that applies to public health pesticides;[8] the preemption analysis therefore begins with a federal requirement that is absent in the case of agricultural pesticides.[9] Accordingly, the same preemption standards mandated by the Supremacy Clause will yield different results in cases involving labels subject to a PMA process than those in cases involving labels not subject to such a PMA process.

CONCLUSION

The rules of conflict preemption compel dismissal here: the state law requirements alleged by Plaintiff are in irreconcilable conflict with the federal requirements imposed on SC Johnson by the EPA under FIFRA. For the foregoing reasons, Defendant respectfully requests reconsideration of this Court's March 21, 2019 Opinion and Order and requests that, on reconsideration, the Court dismiss all claims.

Dated: New York, New York
May 23, 2019

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[8] *See, e.g.*, Joint Statement on Insect Repellents from the EPA and CDC (Jul. 17, 2014), *available at* https://www.epa.gov/sites/production/files/2014-07/documents/joint-epa-cdc-stmnt_3.pdf (EPA's "rigorous [public health] pesticide review process" "ensures that pesticide products that are registered for use against ticks and mosquitoes are effective, including the individual products (such as repellents) used by the general public.").

[9] In his Opposition, Plaintiff cites a litany of agricultural pesticide cases, many involving Monsanto's Roundup product, which are inapposite because of the lack of federal PMA process for the label claims at issue. One Roundup case, *In re Roundup Products Liability Litig.*, 362 F. Supp. 3d 1085 (N.D. Cal. 2019), upheld design defect claims partly on the ground that a state may ban the sale of an unsafe pesticide under FIFRA. The plaintiff there claimed that Roundup was unsafe, and that decision has no bearing on the claims here or on the preemption issue raised by Plaintiff's state-law challenge to label claims reviewed and approved by a federal agency after a PMA process.